FORM PTO-1390 (Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)
RDID0016US	10/088921

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/09175	20 September 2000 (20.09.2000)	25 September 1999 (25.09.1999)

TITLE OF INVENTION
SYSTEM FOR TRANSDERMALLY OBTAINING BODY FLUIDS

APPLICANT(S) FOR DO/EO/US
ESSENPREIS, Matthias; and BOECKER, Dirk

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include itens (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application ~~as filed~~ (35 U.S.C. 371 (c) (2))
   a. ☒ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application ~~as filed~~ (35 U.S.C. 371(c)(2)).
   a. ☒ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). (unexecuted)
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Claims Filed Under Article 34 of the Patent Cooperation Treaty (3pp); Copy of Corrected Ex Offico by IPEA of page 1 of Chapter II Demand indicating Dirk Boecker as co-inventor (1pp); General Appointment of Representative for U.S. Patent and Trademark Office Matters (1pp); and Return postcard

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10/088921	PCT/EP00/09175	RDID0016US

24. The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**		
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$890.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	11 - 20 =	0	x $18.00	**$0.00**	
Independent claims	1 - 3 =	0	x $84.00	**$0.00**	
Multiple Dependent Claims **(check if applicable)**.			☒	**$280.00**	
TOTAL OF ABOVE CALCULATIONS =				**$1,170.00**	
☐ Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				**$0.00**	
SUBTOTAL =				**$1,170.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +				**$0.00**	
TOTAL NATIONAL FEE =				**$1,170.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐				**$0.00**	
TOTAL FEES ENCLOSED =				**$1,170.00**	
				Amount to be: refunded	$
				charged	$

a. ☐ A check in the amount of _____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. **50-0877** in the amount of **$1,170.00** to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **50-0877** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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March 22, 2002
DATE

Atty. Docket No. RDID 0016 US *PATENT*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Essenpreis et al.

Application No.: 10/088,921 Group No.: *To Be Assigned*

Filed: March 22, 2002 Examiner: *To Be Assigned*

For: System for Transdermally Obtaining Body Fluids

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Preliminary to examination of the captioned application, entry of the following amendments and consideration of the following remarks is respectfully requested.

In the specification

Please amend the specification. The amended paragraphs are set forth in the attached Clean Version of Replacement Paragraphs for Entry During Prosecution of US Application No. 10/088,921, as well as a Version with Markings to Show Changes Made.

REMARKS

The specification has been amended to add section headings. No new matter is believed to be added by virtue of the amendments.

It is requested that any fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0016US).

Respectfully submitted,

Date: Dec. 31, 2002

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Clean Version of Replacement Paragraphs for Entry During Prosecution of US Application No. 10/088,921

At page 1, paragraph 1:

BACKGROUND AND SUMMARY OF THE INVENTION
The present invention concerns a system for obtaining body fluid through the skin surface in order to determine one or several analytes in the body fluid obtained in this manner. The body fluid is obtained by firing particles at an area of skin in such a manner that they penetrate as far as the epidermis or dermis. The particles used in the system according to the invention preferably do not contain any amount of the analyte to be determined to avoid a falsification of the analysis. In addition the particles are preferably of such a kind that they can be absorbed by the epidermis or dermis.

At page 9, paragraph 2:

BRIEF DESCRIPTION OF THE DRAWINGS
The present invention is illustrated in more detail by several figures.

At page 10, paragraph 2:

DETAILED DESCRIPTION OF THE DRAWINGS
Diagrams A to C of figure 1 show the penetration of a particle and the discharge of blood. Figure 1A shows the movement of the particle (10) towards the body surface. The figure also shows the skin layers epidermis and dermis. Capillary loops (20) conveying blood are present in the dermis.

Version with Markings to Show Changes Made

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4/pots

System for transdermally obtaining body fluids

The present invention concerns a system for obtaining body fluid through the skin surface in order to determine one or several analytes in the body fluid obtained in this manner. The body fluid is obtained by firing particles at an area of skin in such a manner that they penetrate as far as the epidermis or dermis. The particles used in the system according to the invention preferably do not contain any amount of the analyte to be determined to avoid a falsification of the analysis. In addition the particles are preferably of such a kind that they can be absorbed by the epidermis or dermis.

The present invention is in the field of systems and devices for collecting body fluids from living beings. Nowadays millions of such collections are carried out worldwide to enable medical diagnoses. This field of technology has essentially two domains. In the first domain quantities of liquid in the range of several millilitres are collected with the aid of syringes or so-called vacutainers in order to allow a plurality of examinations to be carried out on the sample of body fluid. In contrast, about 2 to 20 µl of liquids are collected in a second domain in order to carry out so-called rapid tests. This type of rapid testing has gained acceptance particularly in the field of blood sugar measurement. In addition the rapid tests are also used to determine cholesterol, blood lipids, drugs and other analytical parameters. However, blood sugar determinations vastly outnumber the other tests. The reason for this is the relatively high proportion of diabetics in the population, the necessity to frequently measure the blood sugar values and the major medical benefit of knowing the blood sugar values. A periodical control allows the diabetic to detect whether his blood sugar level is outside the normal range and is thus able to take appropriate measures to guide the blood sugar level back into the normal range. In many cases the result of frequently exceeding the blood sugar level is loss of sight and necessitates the amputation of extremities. In recent years it has already been possible to significantly

reduce the number of cases of blindness and amputations by a stricter control of the blood sugar values with the aid of rapid tests. However, blood sugar levels that are too low where the diabetic can fall into a so-called hypoglycaemic shock in which he can become unconscious and die if he is not helped by other persons, can have much more disastrous consequences in the short-term than an excessive blood sugar level.

Without going into more detail about the medical value of other diagnostic rapid tests, it directly follows from the above-mentioned that there is a major need for a wider distribution of diagnostic rapid tests and in particular rapid blood sugar tests. A number of test systems are already available on the market which only require small amounts of capillary blood and give reliable blood sugar test results. The more wide-spread use of such systems is limited less by the costs associated with the testing but is still due to the necessity to withdraw a body fluid for the testing. Thus in recent years there have been a variety of attempts to completely avoid blood withdrawal or to make the blood withdrawal as pain free and comfortable as possible. One instrument for withdrawing blood which already allows a substantially pain free and easy to operate blood withdrawal is described for example in the US Patent RE 35,803. Furthermore there are numerous other instruments on the market for withdrawing blood which are also based on the principle that a relatively small wound is produced by a sharp lancet from which blood emerges. In addition devices are known in the prior art for removing interstitial fluid in which a thin needle is inserted into the dermis and interstitial fluid is pressed out through the needle by applying pressure to the area surrounding the puncture site. A common feature of both methods for removing body fluid is that a lancet or needle remains which has been in contact with the body fluid and is thus contaminated. Since these are extremely sharp objects, the risk of infection by accidental puncturing is relatively high.

The object of the present invention was to provide a relatively painless system for withdrawing small amounts of body fluid which does not need a needle, a cannula or other sharp object that comes into direct contact with the body fluid.

The said object is achieved by a system for transdermally obtaining body fluids which comprises a device that accelerates at least one particle to a speed that allows the particle to penetrate into the skin as far as the epidermis or dermis. The at least one particle should be free of the analyte to be determined to avoid interference with the analysis and in addition the particle is absorbed by the body.

Preferred embodiments of the system according to the invention relate to devices which promote the efflux of the body fluid and means for determining an analyte which are integrated into the system.

The present invention is based on the observation that a penetration of particles into a skin area is often associated with the efflux of blood or interstitial fluid through the skin opening that is formed. This observation is not at all new and is immediately obvious with regard to firearms. However, it is also immediately obvious that it is impossible to directly use firearms or suchlike for the purpose of the present invention since the projectiles are much too large, penetrate too deeply into the body and result in large injuries that are often life-threatening. Furthermore the projectiles used for firearms are not absorbed by the body which makes them unsuitable for the purpose according to the invention.

Devices for the transdermal application of medicaments are known in the prior art in which particles are fired into a skin surface. Such a projectile is known for example from US 4,326,524 which, however, due to its size in the range of several millimetres diameter, is unsuitable for a less painful withdrawal of body fluids. In a number of documents (for example US 5,630,796 and WO 99/04838) it is described that small

particles of medicament can be administered subcutaneously by shooting them into the body. There is no reference in these documents to the fact that firing particles could also be suitable for obtaining body fluids. Furthermore the composition of these particles is geared to the intended therapeutic effect and does not in any way take into consideration a possible interference with an analytical determination.

A system in the sense of the present invention serves to obtain small amounts of body fluids. The amounts of body fluid that are obtained are typically in the range of about 0.1 – 2 µl. Body fluids in the sense of the invention are understood in particular as blood and interstitial fluid (ISF). Blood can be obtained by injuring the capillary network in the boundary layer between the dermis and epidermis or in the dermis. The depth of penetration for this is a depth of about 500 µm depending on the respective person. For withdrawing ISF it is advantageous to allow the particles to penetrate as far as the boundary layer between the epidermis and dermis or somewhat deeper. Within the scope of the present invention penetration depth is understood as the distance between the skin surface and the centre of gravity of the respective particle. The fingertips are a preferred site for collecting capillary blood since the skin openings generated in this area do not immediately close again and hence a sufficient amount of blood can emerge. In contrast blood withdrawal from so-called squamous skin which is for example present on the forearm is less painful. However, additional measures are usually necessary in this case in order to keep a channel generated in the skin surface open to allow the efflux of sufficient blood. However, it is not necessary to damage capillaries in order to withdraw interstitial fluid. According to current knowledge interstitial fluid is an ultrafiltrate of capillary blood in which blood sugar can be detected with the same methods that are used for capillary blood.

A system according to the present invention comprises a device for the transdermal application of particles. For this purpose the particles have to be accelerated to a

speed which is sufficient to allow them to penetrate as far as the epidermis or dermis. Suitable acceleration devices can be based on different principles. It is for example possible to detachably place the particles on a support which is accelerated and remains within the acceleration device whereas the particles detach and penetrate into the body. A device for this purpose which is based on an electromagnetic principle is described in WO 99/04838 to the complete contents of which reference is herewith made. Another method for accelerating the particles to the necessary speeds is to place them on a membrane which is accelerated by a sudden pressure increase. Suitable devices are described for example in US 5,204,253 and US 5,630,796. Reference is made to the complete contents of the above-mentioned documents with regard to methods for accelerating particles. A device for the transdermal application of particles can be designed in principle like the device shown in US 5,630,796 in which a tube is provided whose open end is placed on a region of skin and which is used to create a defined distance between a reservoir for the particles and the skin surface. In accordance with the above-mentioned documents the particles of the present invention could also be located in a reservoir which surrounds the particles in a contamination-free manner and is opened when the acceleration device is actuated.

Within the scope of the present invention it is preferred that the particles are accelerated and allowed to penetrate essentially perpendicular to the skin surface. However, it is also fundamentally possible to apply the particles at an angle to the skin surface.

The particles that are applied transdermally should be essentially free of components that interfere with a subsequent analysis. In particular the particles should be free of the analyte or analytes that are to be determined. On the other hand contamination with the analyte can be tolerated provided the concentration is so small that a subsequent analysis is not significantly falsified. In this connection it is advantageous that a particle dissolution which could lead to a contamination as a rule proceeds

more slowly than an efflux of body fluid. Hence it may be possible to tolerate quantities of the analyte in the particles. A further criterion for the particles is that they should be essentially completely absorbed by the body. Gelatin, sugars, proteins, ice and mixtures of the said substances have proven to be suitable. For a blood sugar (glucose) test it is possible to use sugars such as sucrose, fructose and mannose for the particles. In order to allow an essentially painless collection of body fluid it has proven to be advantageous to use particles having a diameter of less than 700 μm. The particles can for example have a spherical, ellipsoid or disk shape.

As already mentioned, the system according to the invention is particularly suitable for obtaining capillary blood and interstitial fluid. It has turned out that different parameters with regard to particle size and speed are advantageous for these two types of body fluids.

In order to obtain capillary blood it is preferable to use particles having a diameter in the range between 100 and 500 μm since in this size range there is a sufficient probability of already hitting a capillary with one or a few particles. The penetration depth of the particles into the skin should be in the range between 0.5 and 1.3 mm for obtaining capillary blood. It has turned out that such a penetration depth can be achieved with a particle speed in the range from 500 to 1500 m/sec for particles between 100 and 500 μm diameter and having a density of about 1 g/cm^3.

In contrast for obtaining interstitial fluid it is advantageous to use many smaller particles which penetrate to a depth of about 50 to 500 μm. It has proven to be advantageous to use particles having a diameter in the range of 20 to 100 μm which are accelerated to a speed in the range of 500 – 1500 m/sec. In order to deliver an adequate amount of interstitial fluid with particles of this size it is preferable to use 100 – 10 000 particles simultaneously.

An advantage of the system according to the invention is that the skin opening formed by the particles is held open by the particles themselves when the particles come to a standstill at a suitable depth. If only a skin opening would be formed, irrespective of the method, the opening in the region of squamous skin would close by itself which impedes the collection of body fluid.

A system according to the invention can be used in the form described above to convey body fluid to the body surface from where it can be applied to a test element or such like in order to carry out an analytical test. This corresponds to the use of current commercial blood withdrawal devices in which a wound is produced by a lancet and emerging blood is applied by the patient onto a test strip. However, a system according to the invention can also be provided with means which take up the discharged body fluid such as capillaries or capillary-active (absorbent) materials. These means for taking up body fluid are preferably directly connected to a test element for carrying out an analytical test so that the collected body fluid can be transported to the test element. The transport of interstitial fluid to a test membrane using a capillary is described for example in US 5,820,570. A corresponding arrangement for delivering blood via a capillary to a test membrane is described in US 4,637,403.

Within the scope of the present invention it is also advantageous to automatically guide a test element to the site at which the body fluid emerges. As a result it is possible to avoid using a capillary which is an additional disposable component and which is also difficult to manufacture. The test element preferably has an area which can be used to guide it towards the body fluid located on the body surface and which contains no reagent or test chemistry. This prevents chemical substances from entering the body opening. In particular the glucose oxidase used in many tests can lead to irritations.

In addition a system according to the invention can also comprise means for determining an analyte. Such a means can for example be a test element which undergoes a colour change when it is moistened with the analyte. Such a colour change can then be evaluated visually or colorimetrically using a photometer in order to enable a quantitative determination of the analyte. Such test elements and photometers for evaluating them are well known in the prior art and are not described in detail here. Furthermore an analyte can be obtained with the aid of a measuring cell such as an electrochemical measuring cell. Measuring cells are for example commonly used to determine glucose in which glucose oxidase is applied to an electrode and an uncoated metal electrode is used as the counterelectrode. The measured change in potential is due to the formation of hydrogen peroxide on the electrode coated with glucose oxidase. Electrochemical test elements are also known in the prior art as described for example in EP-B-0505475 in which the so-called Cottrell current is determined. This description of devices for determining the analytes is only by way of example. Of course numerous other devices for determining analytes are known to a person skilled in the art which can be used within the scope of the present invention.

Means for determining an analyte can for example be integrated into a system according to the invention by coupling the means for analyte determination to the means for taking up body fluid such that when the means for taking up body fluid is moved to the discharged body fluid, the means for analysis is directly supplied with analyte. In addition the means for analyte determination can also be integrated into the system according to the invention in such a way that it is either so close to the site where the body fluid is discharged that it is directly supplied with body fluid or the means for analysis can be moved to the body fluid for example by a movable arrangement of the means for analyte determination within the system.

Within the scope of the present invention it is also advantageous to provide means for promoting the discharge of body fluid. In figure 2 of US 5,820,570 an arrangement is described in which the bottom edge of a housing, which is at a lateral distance from the site of body fluid withdrawal, is pressed onto the body surface and in this manner body fluid is pressed out of the tissue. A method for withdrawing body fluids is also described in WO 97/42886 in which the housing of a blood withdrawal instrument is repeatedly pressed against the body surface in such a manner that a ring of tissue is pressed down in order to press body fluid out of the exit site. Furthermore a method and a device are described in US 3,626,929 in which a wound is produced on a fingertip and the proximal part of the finger is periodically pressed to promote the discharge of blood. In the scope of the present invention means for promoting discharge of body fluid should encompass devices which exert pressure on an area of skin which is adjacent to the area of skin into which the at least one particle has penetrated. Furthermore means are also included which comprise an ultrasonic device as described for example in WO 94/08655 and US 5,458,140. Finally means are also included which have a device for applying an underpressure to the area of skin in which the at least one particle has penetrated to promote the discharge.

The present invention is illustrated in more detail by several figures.

Figure 1: Penetration of a particle into an area of skin and discharge of blood.

Figure 2: Electromagnetic system for accelerating particles.

Figure 3: Detachable attachment of particles.

Figure 4: Packaging for particles.

Figure 5: Packaging shown in figure 4 in cross-section.

Figure 6: Electromagnetic system for accelerating a single particle or several particles.

Diagrams A to C of figure 1 show the penetration of a particle and the discharge of blood. Figure 1A shows the movement of the particle (10) towards the body surface. The figure also shows the skin layers epidermis and dermis. Capillary loops (20) conveying blood are present in the dermis.

Diagram B shows a state in which the particle has penetrated through the epidermis and becomes lodged in the dermis. On entry into the dermis the capillary loops that are shown have been partially damaged so that blood can escape from them. Figure 1C shows how blood from the capillary loops emerges from the skin through the opening created by the particle and a blood drop (30) is formed on the skin surface.

Figures 2 to 6 show systems for accelerating particles which are taken from the International Application WO 99/04838.

Figure 2 shows an electromagnetic system for accelerating the particles (10). A thin ribbon of metal (101) is arranged such that it results in opposing areas of the band. If a current pulse is applied to the ends of the metal ribbon, the opposing parts of the metal ribbon are repelled due to the generated electromagnetic fields. The lower part of the metal ribbon is in contact with an abutment (102) so that it cannot be deflected downwards. Accordingly the upper part of the metal ribbon is catapulted upwards by the electromagnetic repulsion as shown in figure 2B. Particles (10) are located in a reservoir which is sealed by a plastic skin (103). The plastic skin has a predetermined breaking point (104) which is torn open when the upper part of the metal ribbon is repelled. As a result the particles (10) are released and fly at a speed which is essentially determined by the speed of the metal ribbon, onto a body surface from where they penetrate into the skin.

Figure 3 shows an alternative attachment for the particles. In this case the particles are releasably attached to a surface (110). The surface (110) can be a double-coated adhesive tape which is in turn attached to a plate (111). The plate (111) can be accelerated in the direction of the particles and when the plate brakes the particles are released from the surface (110) as a result of their inertia and fly towards the skin surface. The plate (111) can for example be accelerated mechanically by a spring located on the side opposite to the particles, by a pressure pulse or by the electromagnetic method shown in figure 2. A further method is to use a plate which has a depression in the area shown in figure 3 and is planar in the remaining area of the plate. When two opposing ends of the plate are bent towards the depression, the depression suddenly buckles forwards as a result of the mechanical tension as shown in figure 3 and accelerates the particles.

Figure 4 shows a further possible reservoir for particles that can for example be used in conjunction with the device shown in figure 2. The particles are located in a plastic container whose ends are closed by folds and has a predetermined breaking point in the middle. When the support plate (101) is accelerated and subsequently decelerated, the reservoir (103) tears open along the predetermined breaking point (104) and releases the particles. This is shown in more detail in figure 5.

Figure 6 shows an interchangeable module with a reservoir for particles. The arrangement is based on the electromagnetic propulsion method that has already been described above in connection with figure 2. The particles (10) are located in the depression (101a) of an electrically conductive ribbon (101) which is arranged in an M-shape in the present example. If a current impulse is applied to the contacts (105), the opposing arms of the electrically conductive ribbon are repulsed and the outer regions are pressed against the walls (106) of the housing (108). The outward movement of the arms stretches the U-shaped part of the ribbon in which the particle (10) is located and the particle (10) is propelled upwards out of the housing. The

module shown in figure 6 also has a sealing foil (109) which seals the space in which the particles are located to the outer space. This can ensure the sterility of the particles that penetrate the body. The sealing foil (109) is removed before using the module to introduce the particles into the body.

Claims

1. System for transdermally obtaining body fluid to determine at least one analyte comprising

a device for the transdermal application of 1 to 10 particles having a diameter between 100 and 500 µm comprising an acceleration device which simultaneously accelerates the particle(s) to a speed in the range of 500 to 1500 m/s that allows the particle(s) to penetrate into an area of skin as far as the epidermis or dermis, and said device comprising a trigger mechanism to trigger the acceleration device,

a reservoir for the particle(s) and
a means to promote the efflux of body fluid from an area of skin.

2. System as claimed in claim 1, in which the particle(s) is/are essentially free of the at least one analyte to be determined.

3. System as claimed in claim 1, in which the particle(s) is/are of such a kind that it/they can be essentially completely absorbed.

4. System as claimed in claim 1, in which the particle(s) is/are essentially composed of gelatin.

5. System as claimed in claim 1, comprising means for taking up body fluid.

6. System as claimed in claim 5, in which the means for taking up body fluid is a capillary or a capillary-active material.

7. System as claimed in claim 1 or 5, comprising means for determining an analyte.

8. System as claimed in claim 1, in which the means for promoting the efflux is an ultrasonic device.

9. System as claimed in claim 1, in which the means for promoting the efflux is a device for applying an underpressure to the skin area.

10. System as claimed in claim 1, in which the means for promoting the efflux is a device for applying pressure to a second skin area which is adjacent to the skin area in which the particle(s) has/have penetrated.

amended page

Abstract

The invention concerns a system for transdermally obtaining body fluid to determine at least one analyte comprising a device for transdermally applying at least one particle having an acceleration device which accelerates the at least one particle to a speed which enables the particle to penetrate into an area of skin as far as the epidermis or dermis and a trigger mechanism to trigger the acceleration device and a reservoir for the at least one particle. The particles used in the system are preferably designed such that they are absorbed by the body.

Fig. 1

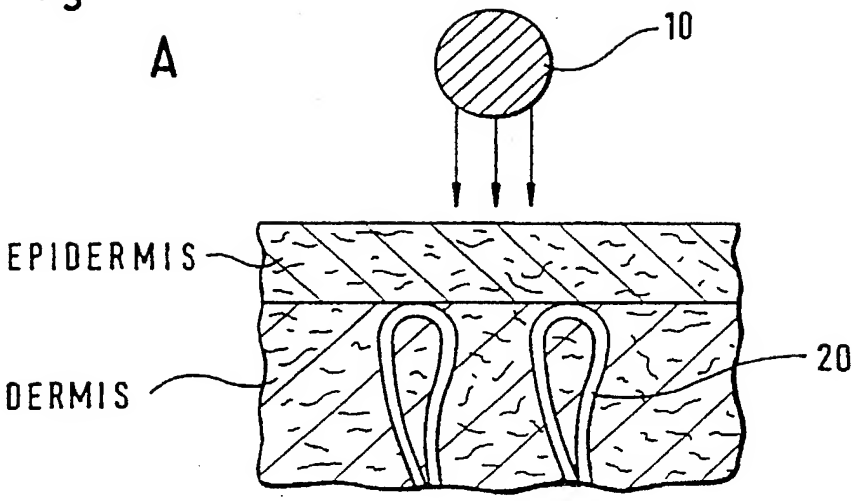

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Fig. 2

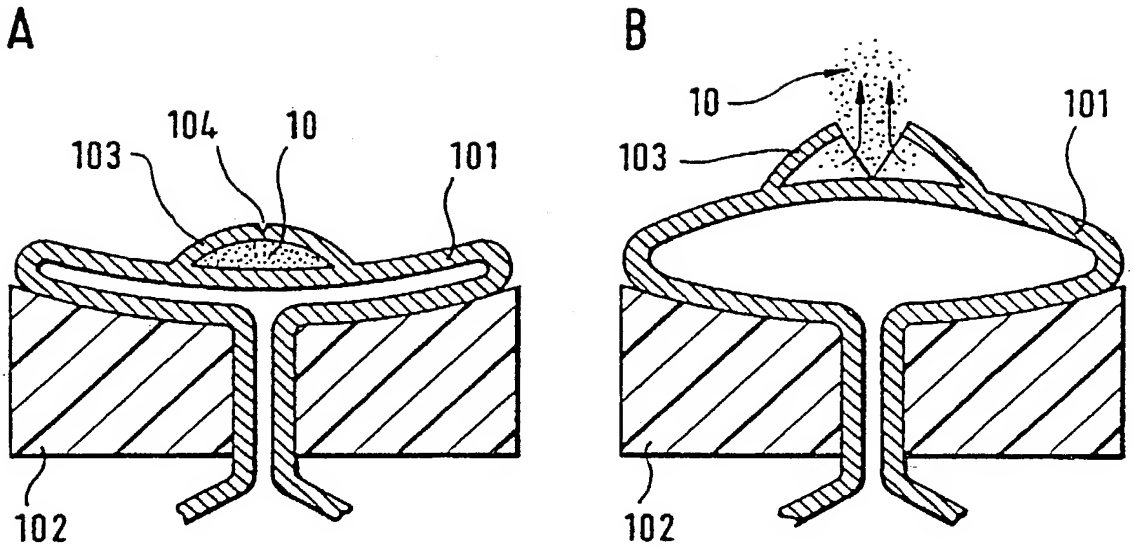


Fig. 3

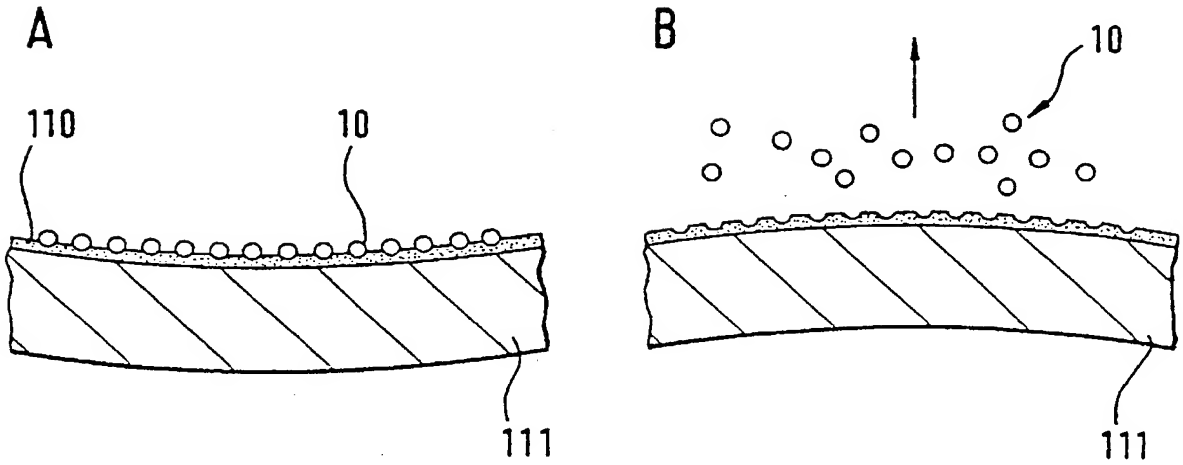


Fig. 4

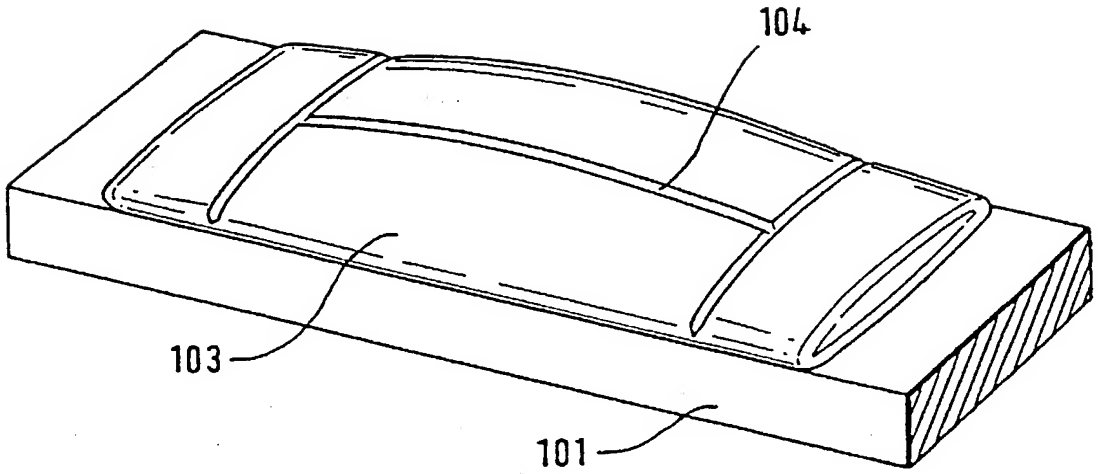


Fig. 5

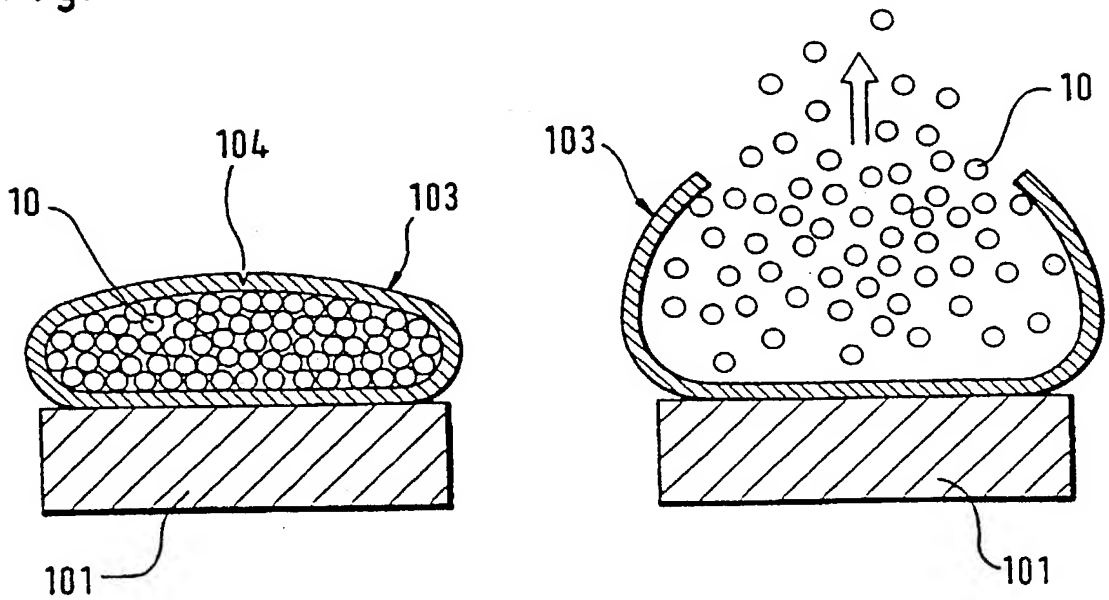
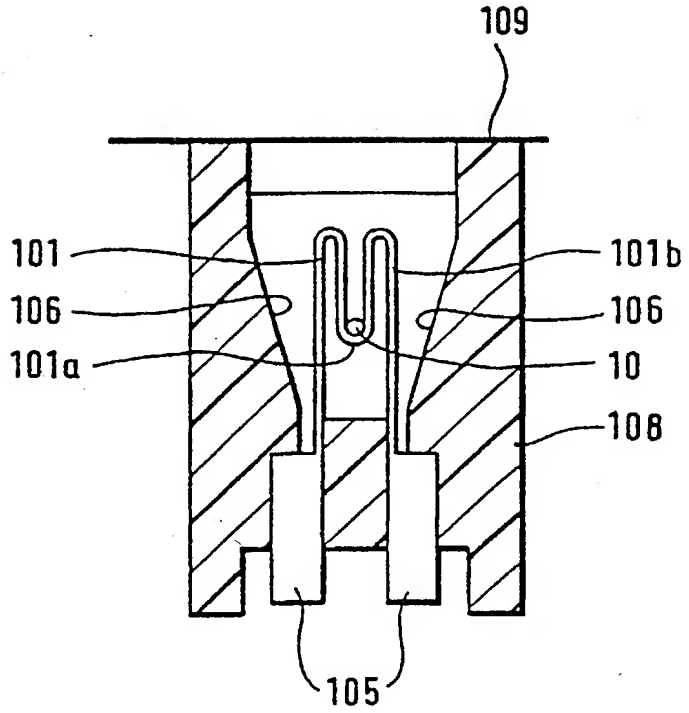


Fig. 6



Docket No.
RDID0016US

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled
SYSTEM FOR TRANSDERMALLY OBTAINING BODY FLUIDS

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on **March 22, 2002** as United States Application No. or PCT International Application Number **10/088,921**

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
PCT/EP00/09175	**PCT**	**20/09/2000**	☐
(Number)	(Country)	(Day/Month/Year Filed)	
19946059.0	**Germany**	**25/09/1999**	☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

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POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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